

1 Cabinet for Health and Family Services

2 Office of Health Policy

3 (Amendment)

4 900 KAR 6:125. Certificate of Need annual surveys, and registration requirements for
5 new Magnetic Resonance Imaging units.

6 RELATES TO: KRS 216B.010, 216B.020(2)(a), 216B.040

7 STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 216B.040(2)(a)1

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the
9 Cabinet for Health and Family Services to administer Kentucky's Certificate of Need
10 Program and to promulgate administrative regulations as necessary for the program.
11 This administrative regulation establishes the requirements for registration of Magnetic
12 Resonance Imaging units and the requirements for submission of annual survey data
13 that are used to produce annual reports necessary for the orderly administration of the
14 Certificate of Need Program.

15 Section 1. Definitions.

16 (1) "Cabinet" is defined by KRS 216B.015(6).

17 (2) "Days" means calendar days, unless otherwise specified.

18 (3) "Exempt practitioners [physicians]" means physicians, dentists, and other
19 practitioners of the healing arts that meet the exemption established in KRS
20 216B.020(2)(a) and that operate a Magnetic Resonance Imaging unit.

21 (4) "Long term care facility" means any entity with licensed long term care beds

1 including nursing facility, nursing home, intermediate care, Alzheimer's, intermediate
2 care facility for the mentally retarded, or personal care.

3 (5) "Office of Inspector General" means the office within the Cabinet for Health and
4 Family Services that is responsible for licensing and regulatory functions of health
5 facilities and services.

6 (6) "Owner" means a person as defined in KRS 216B.015(22)(21) who is applying
7 for the certificate of need and will become the licensee of the proposed health service or
8 facility.

9 (7) "Year" means a calendar year from January 1 through December 31.

10 Section 2. Entities Completing Surveys. The following entities shall submit annual
11 surveys:

12 (1) Licensed ambulatory surgery centers;

13 (2) Licensed hospitals performing ambulatory surgery services [or performing
14 outpatient surgical services];

15 (3) Licensed home health agencies;

16 (4) Licensed hospice agencies;

17 (5) Licensed hospitals;

18 (6) Licensed private duty nursing agencies;

19 (7) Facilities with licensed long term care beds;

20 (8) Entities that hold a certificate of need for MRI equipment;

21 (9) Facilities with megavoltage radiation equipment;

22 (10) Licensed psychiatric residential treatment facilities; and

23 (11) Facilities with positron emission tomography equipment.

1 Section 3. Entities Completing Surveys on a Voluntary Basis. Exempt practitioners
2 [~~physicians~~] that have MRI equipment may submit surveys on a voluntary basis.

3 Section 4. Annual Survey Submission Including Entities Completing Surveys on a
4 Voluntary Basis. Exempt practitioners [~~physicians~~] that have MRI equipment shall
5 submit surveys on a voluntary basis. An annual survey shall be completed for the
6 previous year and transmitted electronically by accessing the Office of Health Policy's
7 Web site at <https://prd.chfs.ky.gov/OHPSurvey/>.

8 Section 5. Surveys shall be submitted annually as follows:

9 (1) Kentucky Health Survey Registry 2013 [~~2012~~] Ambulatory Surgery II;

10 (2) Kentucky Health Survey Registry 2013 [~~2012~~] Home Health II;

11 (3) Kentucky Health Survey Registry 2013 [~~2012~~] Hospice;

12 (4) Kentucky Health Survey Registry 2013 [~~2012~~] Hospital [~~Annual Survey of~~
13 ~~Licensed Hospitals~~];

14 (5) Kentucky Health Survey Registry 2013 [~~2012~~] Private Duty Nursing;

15 (6) Kentucky Health Survey Registry 2013 [~~2012~~] Long Term Care;

16 (7) Kentucky Health Survey Registry 2013 [~~2012~~] Magnetic Resonance Imaging;

17 (8) Kentucky Health Survey Registry 2013 [~~2012~~] Megavoltage Radiation (Linear
18 Accelerator);

19 (9) Kentucky Health Survey Registry 2013 [~~2012~~] Psychiatric Residential Treatment
20 Facility; and

21 (10) Kentucky Health Survey Registry 2013 [~~2012~~] Positron Emission Tomography.

22 Section 6. Annual surveys shall be completed and submitted no later than March
23 15th of each year. If the 15th falls on a weekend or holiday, the submission due date

1 shall be the next working day.

2 Section 7. Extensions for Survey Submission. (1) A request for an extension for
3 submission of data shall be made in writing or via email to the Office of Health Policy
4 ~~[administrator of the specific survey]~~.

5 (2) The request for an extension shall state the facility name, survey log-in
6 identification number, contact person, contact phone number, contact email address,
7 and a detailed reason for the requested extension.

8 (3) One (1) extension per survey of up to ten (10) days shall be granted.

9 (4) An additional extension shall only be granted if circumstances beyond the
10 entity's control prevents timely completion of a survey.

11 Section 8. Data Corrections to Draft Annual Reports Utilizing Data Submitted in the
12 Annual Surveys. (1)(a) Prior to the release of a draft report to a facility for its review, the
13 Office of Health Policy shall review data for completeness and accuracy.

14 (b) If an error is identified, the facility shall be contacted by the Office of Health
15 Policy and allowed fourteen (14) days to make corrections.

16 (2)(a) Prior to publication of the reports, the Office of Health Policy shall publish draft
17 reports available only to the entities included in each individual report.

18 (b) Each facility shall be notified of a Web site and provided with a login
19 identification and password required to access each applicable draft report and shall
20 have fourteen (14) days to review the data for errors.

21 (c) Corrections shall be submitted in writing or via email to the Office of Health
22 Policy before the expiration of the fourteen (14) day review period.

23 (3)(a) After publication of the reports, reports shall not be revised as a result of data

1 reported to the Office of Health Policy incorrectly by the facility.

2 (b) Corrections received after the fourteen (14) day review period shall not be
3 reflected in the published report.

4 (c) A facility may provide a note in the comments section for the following year's
5 report, referencing the mistake from the previous year.

6 Section 9. Annual Reports. (1) Utilizing data submitted in the annual surveys, the
7 Office of Health Policy shall publish reports annually as follows:

8 (a) Kentucky Annual Ambulatory Surgical Services Report;

9 (b) Kentucky Annual Home Health Services Report;

10 (c) Kentucky Annual Hospice Services Report;

11 (d) Kentucky Annual Hospital Utilization and Services Report;

12 (e) Kentucky Annual Private Duty Nursing Agency Report;

13 (f) Kentucky Annual Long Term Care Services Report;

14 (g) Kentucky Annual Magnetic Resonance Imaging Services Report;

15 (h) Kentucky Annual Megavoltage Radiation Services Report;

16 (i) Kentucky Annual Psychiatric Residential Treatment Facility Report; and

17 (j) Kentucky Annual Positron Emission Tomography Report.

18 (2) Electronic copies of annual reports may be obtained at no cost from the Office of
19 Health Policy's Web site at <http://chfs.ky.gov/ohp/dhppd/dataresgal.htm>. A paper copy
20 may be obtained for a fee of twenty (20) dollars at the Cabinet for Health and Family
21 Services, Office of Health Policy, 275 East Main Street 4WE, Frankfort, Kentucky
22 40621.

23 Section 10. Any facility, other than an exempt practitioner [physician] that has MRI

equipment, that fails to complete a required annual survey shall be referred to the Office of Inspector General for further action which may impact the facility's license renewal as provided for in 902 KAR 20:008, Section 2(6).

Section 11. Magnetic Resonance Imaging Equipment Registration on a Voluntary Basis by Exempt Practitioners [Physicians] that have MRI Equipment. (1) An exempt practitioner [physician] who uses a Magnetic Resonance Imaging unit (MRI) may register the MRI equipment by disclosing the following information by telephone contact and followed up in writing to the Office of Health Policy [~~Cabinet for Health and Family Services~~]:

(a) Name, address, and telephone number of the facility at which each unit is located or to be utilized;

(b) Identification of designated contact person or authorized agent of each facility;

(c) Make, model, and serial number of each unit;

(d) Date the unit became operational at each site; and

(e) Whether the unit is free-standing or mobile. If the unit is mobile, the submission shall also identify the number of days the unit is operational.

(2) Within thirty (30) days of a change in the facility's address, the addition of another MRI unit, or the discontinuation of any unit, the designated contact person or authorized agent shall notify the Office of Health Policy in writing.

Section 12. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Kentucky Health Survey Registry 2013 [~~2012~~] Ambulatory Surgery II", screen prints [~~dated August 23, 2012~~];

(b) "Kentucky Health Survey Registry 2013 [2012] Home Health II", screen prints
[dated August 23, 2012];

(c) "Kentucky Health Survey Registry 2013 [2012] Hospice", screen prints [dated
August 23, 2012];

(d) "Kentucky Health Survey Registry 2013 [2012] Hospital", screen prints [dated
August 23, 2012];

(e) "Kentucky Health Survey Registry 2013 [2012] Private Duty Nursing", screen
prints [dated August 23, 2012];

(f) "Kentucky Health Survey Registry 2013 [2012] Long Term Care", screen prints
[dated August 23, 2012];

(g) "Kentucky Health Survey Registry 2013 [2012] Magnetic Resonance Imaging",
screen prints [dated August 23, 2012];

(h) "Kentucky Health Survey Registry 2013 [2012] Megavoltage Radiation (Linear
Accelerator)", screen prints [dated August 23, 2012];

(i) "Kentucky Health Survey Registry 2013 [2012] Psychiatric Residential Treatment
Facility", screen prints [dated August 23, 2012]; and

(j) "Kentucky Health Survey Registry 2013 [2012] Positron Emission Tomography",
screen prints [dated August 23, 2012];

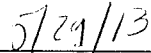
(2) This material may be inspected, copied, or obtained, subject to applicable
copyright law, at the Cabinet for Health and Family Services, 275 East Main Street,
Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

900 KAR 6:125

APPROVED:

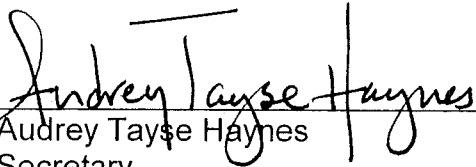


Emily Whelan Parento
Executive Director
Office of Health Policy

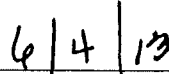


Date

APPROVED:



Audrey Tayse Haynes
Secretary
Cabinet for Health and Family Services



Date

900 KAR 6:125

PUBLIC HEARING AND COMMENTS:

A public hearing on this administrative regulation shall, if requested, be held on July 22, 2013, at 9:00 a.m. in the Auditorium A, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by July 15, 2013, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until July 31, 2013. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Tricia Orme, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573

REGULATORY IMPACT ANALYSIS AND TEIRING STATEMENT

Administrative Regulation Number: 900 KAR 6:125

Contact Person: Diona Mullins (502) 564-9592

1. Provide a brief summary of:
 - (a) What this administrative regulation does: This administrative regulation establishes the requirements for completion of annual surveys with the Office of Health Policy. It also establishes voluntary registration of practitioner owned Magnetic Resonance Imaging (MRI) units as well as voluntary submission of annual surveys by physicians owning CON-exempt MRI units.
 - (b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statute, KRS 216B.010, 216B.062, 216B.990.
 - (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 216B.010, 216B.062 and 216B.990 by establishing the requirements for completion of annual surveys, the voluntary registration of new magnetic resonance imaging units, and voluntary completion of annual surveys by physician exempt MRI units with the Office of Health Policy for the orderly administration of the certificate of need program.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of KRS 216B.010, 216B.062 and 216B.990 by establishing the requirements for completion of annual surveys and the voluntary requirement of practitioner owned MRI units to register with the Office of Health Policy
2. If this is an amendment to an existing administrative regulation, provide a brief summary of:
 - (a) How the amendment will change this existing administrative regulation: The amendment incorporates by reference the 2013 annual surveys.
 - (b) The necessity of the amendment to this administrative regulation: This amendment is necessary to provide the 2013 version of the annual surveys to entities required to submit annual surveys.
 - (c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of the authorizing statutes by providing the 2013 version of the annual surveys..
 - (d) How the amendment will assist in the effective administration of the statutes: This amendment will provide the 2013 version of the annual surveys.

3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects an entity required to submit annual surveys and an entity wishing to voluntarily register a Magnetic Resonance Imaging unit. Approximately 899 entities complete a survey each year.
4. Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
 - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Each entity required to submit an annual report shall complete the annual survey online by March 15, 2014.
 - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There is no charge to complete the survey.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in Question 3: The entities will now have updated surveys for collection of 2013 data and will have access to the published reports which include the reported utilization of all providers in a specific category.
5. Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:
 - (a) Initially: No cost
 - (b) On a continuing basis: No cost
6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The source of funding to be used for the implementation and enforcement of this administrative regulation will be the Office of Health Policy's existing budget. As stated above, the annual survey process and voluntary registration of MRI units identified in the administrative regulation are already used as part of our normal operations, therefore no additional funding will be required.
7. Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary.
8. State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation establishes a \$20.00 fee for a paper copy of the published utilization report. An increase in the fee is not proposed.

9. TIERING: Is tiering applied? (Explain why or why not)
Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 900 KAR 6:125 Contact Person: Diona Mullins 502-564-9592

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This amendment may impact any government owned health care facilities which are required to submit annual utilization reports.
2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.010, 216B.062, and 216B.990.
3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
 - (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation includes a \$20.00 fee for anyone wishing to purchase a paper copy of an annual report. As the reports are available electronically at no cost, the fee is necessary to recoup the agency's printing costs incurred in producing paper reports; therefore, any revenue generated will simply cover the printing costs. We anticipate that approximately 40 reports will be purchased for total revenue of \$800.00.
 - (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation includes a \$20.00 fee for anyone wishing to purchase a paper copy of an annual report. As the reports are available electronically at no cost, the fee is necessary to recoup the agency's printing costs incurred in producing paper reports; therefore, any revenue generated will simply cover the printing costs. We anticipate that approximately 40 reports will be purchased for total revenue of \$800.00.
 - (c) How much will it cost to administer this program for the first year? No additional costs will be incurred to implement this regulation.
 - (d) How much will it cost to administer this program for subsequent years? No additional costs will be incurred to implement this regulation for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):
Other Explanation:

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
Office of Health Policy

900 KAR 6:125. Certificate of Need annual surveys, and registration requirements for new Magnetic Resonance Imaging units.

Summary of Changes to Material Incorporated by Reference

1. Annual surveys are required to be completed on-line. Copies of the on-line screens to be used by facilities in 2013 are incorporated by reference.
2. In all surveys, references to 2012 have been revised to 2013 and references to 2013 have been revised to 2014.
3. "Kentucky Health Survey Registry 2013 Ambulatory Surgery II" is used by licensed ambulatory surgery centers and licensed hospitals performing ambulatory surgery services to submit annual survey information.
 - Page 5, Section I, A- After 1st paragraph- Insert new bullet to indicate that Sec I: A-E should not include procedure room data.
 - Page 7, Section II, A-After 1st paragraph- Insert new bullet to indicate that Sec II: A-E should include procedure room data only.

The screen prints consist of 9 pages.

4. "Kentucky Health Survey Registry 2013 Home Health II" is used by licensed home health agencies to submit annual survey information.
 - Page 8, Section I - In 1st paragraph, clarify that this section also includes traditional private duty nursing.

The screen prints consist of 16 pages.

5. "Kentucky Health Survey Registry 2013 Hospice" is used by licensed hospices to submit annual survey information. No revisions were made to the questions asked within the survey.

The screen prints consist of 7 pages.

6. "Kentucky Health Survey Registry 2013 Hospital" is used by licensed hospitals to submit annual survey information.
 - Page 5, Instructions-Add language to clarify that Line C shall also include Level IV neonatal.

- Page 5, Service Unit column- Add language to clarify that licensed or allocated psych beds shall be reported.
- Page 7, Beds and Utilization by Licensure Category-Add categories for Neonatal II, III, and IV, General Psych, Child Psych, Adolescent Psych, Adult Psych and Geriatric Psych. Add new column for "General Psych Allocated As:".

The screen prints consist of 17 pages.

7. "Kentucky Health Survey Registry 2013 Private Duty Nursing" is used by licensed private duty nursing agencies to submit annual survey information. No revisions were made to the questions asked within the survey.

The screen prints consist of 9 pages.

8. "Kentucky Health Survey Registry 2013 Long Term Care" is used by licensed long term care facilities to submit annual survey information.
 - Pages 4-9 were revised to include a separate reporting category for Continuing Care Retirement Community (CCRC) nursing home bed utilization.

The screen prints consist of 10 pages.

9. "Kentucky Health Survey Registry 2013 Magnetic Resonance Imaging" is used by entities which hold a certificate of need for MRI equipment and exempt practitioners that have MRI equipment to submit annual survey information.
 - Page 6, MRI Service Section-Added language to distinguish between relocatable unit and licensed mobile health service

The screen prints consist of 8 pages.

10. "Kentucky Health Survey Registry 2013 Megavoltage Radiation (Linear Accelerator) is used by facilities with Megavoltage Radiation equipment to submit annual survey information.
 - Page 5, MEG Section- Add line "Total Patients Served:".

The screen prints consist of 6 pages.

11. "Kentucky Health Survey Registry 2013 Psychiatric Residential Treatment Facility" is used by licensed psychiatric residential treatment facilities to submit annual survey information.

- Page 4, Psychiatric Residential Treatment Facility, 2nd paragraph of instructions- Added the following: "All items must be completed with actual and tabulated data before this survey will be considered acceptable. Surveys are due March 15, 2014."
- Page 5, Psychiatric Residential Treatment Facility Utilization-Added language to last bullet regarding age groups to clarify that a patient should be placed in the age group in which they belong a of December 31 or when they were discharged. All of the patient days to with the child when the age group changes.

The screen prints consist of 10 pages.

12. "Kentucky Health Survey Registry 2013 Positron Emission Tomography" is used by facilities with Positron Emission Tomography equipment to submit annual survey information.

- Page 5, PET Service Section- Add language to clarify that hospitals and specialized medical technology services (SMTS) providing services under their CON or license should report all utilization as fixed, including utilization of relocatable units.

The screen prints consist of 7 pages.

13. The total number of pages incorporated by reference is 99 pages.